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Q&A: Former Federal Prosecutor Explains New DOJ Initiative To Crack Down on Opioid Fraud



The Department of Justice (DOJ) recently implemented a pilot program intended to crack down on physicians, pharmacists, drug manufacturers and anyone else in the opioid supply chain found guilty of prescribing the drugs in a medically irresponsible manner.

Adam Overstreet, JD, a counsel in the health care practice group at Burr & Forman LLP, in Birmingham, Ala., who previously spent 10 years as a federal prosecutor for the U.S. Attorneys, Southern District of Alabama prosecuting health care and white-collar crime, spoke with *Pain Medicine News* to explain the impetus behind the program, how it works, the consequences pain physicians might face if found to be prescribing irresponsibly, and best practices for responsible physicians to protect themselves from prosecution.

PMN: What is the DOJ's new program for curbing opioid abuse, and how did it come about?

Dr. Overstreet: The Opioid Fraud and Abuse Detection Unit was established in late 2017 through an announcement by Attorney General Jeff Sessions.



Adam Overstreet, JD

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Probably one of the main driving forces that led to the formation of this unit was the increased amount of opioid drug overdose deaths every year; it's increased exponentially each year, and then in 2016, there were a little more than 60,000 deaths. I think that the hope is to reduce instances of physicians prescribing opioids outside of medical norms and ultimately to dramatically reduce the number of deaths.

***PMN:* Who, specifically, is the DOJ concerned with prosecuting?**

Dr. Overstreet: So far, the focus has been on physician practices and so-called pill mills, but the mandate extends to every type of pain management practitioner, whether that's nurse practitioners, pharmacists or drug manufacturers. The overall intent seems to be to crack down on pill mills in particular and reduce the number of deaths, and even hospitalizations. One way that's being done is to assign a specially allocated opioid prosecutor to each district, and that person will lead the charge, so to speak, in each office, to formalize a strategy to meet the DOJ's initiatives.

***PMN:* How is a "pill mill" defined according to the DOJ?**

Dr. Overstreet: In the DOJ's eyes, a pill mill is any physician or practitioner who has basically abandoned medical principles and is prescribing drugs for the purposes of making money. That could extend to pharmacies and drug manufacturers as well.

One thing that the DOJ is emphasizing is the use of data analytics—for instance, Mr. Sessions just announced within the last year that there is going to be an influx of Drug Enforcement Administration (DEA) agents who are going to analyze statistics and see which manufacturers, practitioners and pharmacists are statistical outliers, who are prescribing or moving what the DOJ considers an inordinate amount of opioids and controlled substances. That includes reports from drug manufacturers to see where opioids are going, but also prescription drug monitoring program (PDMP) data, which is a gold mine for these types of investigations. And that helps the DOJ focus their attention on potential targets.

To provide one recent example, the House Energy and Commerce Committee is separately investigating the opioid industry, and they recently announced that during a 10-year period, drug distribution companies had shifted more than 20 million pain pills to two pharmacies that were just four blocks apart in a small West Virginia town with a population of 2,900 people. So that's the type of data that will draw the DOJ's attention as part of these investigations.

***PMN:* In addition to analyzing data, what other means does the DOJ have of investigating pill mills?**

Dr. Overstreet: It's heavily data driven—that's where it starts—but they also have investigators who are trained to look at a number of red flags. It starts primarily with volume, but they also look at these telltale signs that maybe a practice is operating as a pill mill. They'll sometimes stake out a clinic to just see the number of patients there, to see whether there's a long line of people waiting outside to obtain their prescriptions. At certain times they will conduct undercover investigations where an agent will pose as a patient and come into the facility to see whether they can get opioid prescriptions, to see whether there's a physician who's actually there to treat them. They'll tell physicians they're diverting or are addicted to drugs and see whether the physician will still prescribe to them. Those are the kinds of things they look at, in addition to just numbers.

For example, I helped prosecute a large pill mill case in southern Alabama. There were two doctors involved, and the PDMP data reflected that they were the top two prescribers in the nation of two brands of fentanyl. Basically, those drugs are intended to be used only by cancer patients who are having breakthrough pain and are resistant to other opioids, but the data showed that these doctors were prescribing them in large quantities for standard conditions like back and neck pain. That gives you an idea of how PDMP data can come into play during an investigation.

***PMN:* When physicians are found culpable of operating pill mills, what kinds of consequences do they face?**

Dr. Overstreet: It varies. It depends on whether they're prosecuted criminally, civilly or administratively. In terms of a criminal prosecution, you're looking at potential jail time, and that range varies from case to case. Also, in a criminal case, you're subject to forfeiture of any assets that the government maintains you obtained as a result of your pill mill operation. For instance, in the example I just mentioned, both doctors received 20 years in prison after conviction by a jury, and they forfeited a number of assets: property, luxury cars and bank accounts.

The time given to someone who's convicted is based on the amount of drugs the government says they distributed. If the government can prove that people died as a result of taking drugs from the physician, the doctor can then face severe penalties, usually no less than 20 years and up to life. It varies widely in terms of criminal liability, based on what the government can prove.

There's civil liability to consider as well. For example, there is a type of lawsuit called a whistleblower lawsuit, where an employee or former employee of the practice turns the practice in for prescribing unnecessary medications. The government can then potentially sue the practice and collect monetary damages under the False Claims Act, a federal statute that provides for the government to sue medical providers who submit alleged false claims to the government for reimbursement. There's also administrative repercussions to consider: The DEA, for instance, could require the physician to forfeit his or her DEA certification, effectively putting an end to the practice. A physician could be subject to punishment from their state medical board, including the revocation of their medical license.

PMN: What can responsible physicians do to ensure they don't attract the DOJ's attention?

Dr. Overstreet: I tell physicians to use their best judgment and prescribe what is reasonable and medically necessary in the context of the patient's presentation. The most important thing is to carefully document all treatment. Make sure you consider alternatives to opioids, that you conduct thorough medical exams, and that you prescribe the lowest doses of opioids when possible. Make efforts to monitor patients for signs of addiction and diversion. You might even have regular audits—look at your records from the perspective of the government. If doctors implement these kinds of practices, they're much less likely to be caught up in any type of investigation.

—Interview conducted by Ajai Raj